510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
k052520

B. Purpose for Submission:
New device

C. Measurand:
Amphetamine, methamphetamine, benzoylecgonine, morphine, tetrahydrocannabinol (THC), and phencyclidine (PCP)

D. Type of Test:
Qualitative immunoassay

E. Applicant:
Tianjin New Bay Bioresearch Co., Ltd.

F. Proprietary and Established Names:
Forsure One Step Multiple (Up to Six) Drug Screen Test Card

G. Regulatory Information:

1. Regulation sections:
   21 CFR 862.3100, 862.3610, 862.3250, 862.3640, 862.3870
2. Classification:
   All class II
3. Product Codes:
   DKZ, DJC, DIO, DPK, LDJ, LCM
4. Panel:
   Toxicology (91)

H. Intended Use:

1. Intended use(s):
   Refer to Indications for use.

2. Indication(s) for use:
   The Forsure One Step Multiple (Up to Six) Drug Screen Test Card is a prescription assay intended for professional use in central laboratories only. It provides qualitative screening results for Amphetamine (AMP), Methamphetamine (MET), Bezoylecgonine (BEG/COC), 11-nor-Δ-9-Tetrahydrocannabinol-9-carboxylic acid (THC), Morphine (MOR/OPI) and Phencyclidine (PCP) in human urine at cut off concentrations of AMP 1000 ng/ml, MET 1000 ng/ml, BEG 300 ng/ml, THC 50ng/ml, MOR 2000 ng/ml

and PCP 25ng/ml. The device may include as few as one and as many as six individual assays. For In Vitro Diagnostic Use.

This assay provides only a preliminary result. Clinical consideration and professional judgment should be applied to any drugs of abuse test result, particularly in evaluating a preliminary positive. To obtain a confirmed analytical result, a more specific alternate chemical method is needed. Gas chromatography/mass spectroscopy (GC/MS) is the recommended confirmatory method.

3. Special condition for use statement(s):
   This assay provides only a preliminary result. Clinical consideration and professional judgment should be applied to any drugs of abuse test result, particularly in evaluating a preliminary positive. To obtain a confirmed analytical result, a more specific alternate chemical method is needed. Gas chromatography/mass spectroscopy (GC/MS) is the recommended confirmatory method.

   Certain foods or medications may interfere with tests for amphetamines and opiates and cause false positive results.

4. Special instrument Requirements:
   Not applicable. The device is a visually read single-use device.

I. Device Description:

The product is a single-use device in which one or two strips are inserted into a cassette. Each of the strips contains reagents that test for one to three drugs; therefore the device can test as few as one or as many as six drugs at a time. Operators add several drops of the sample to the sample well. The test reaction is initiated by movement of the sample through the test strip.

Description of the test antibodies: monoclonal mouse antibody against amphetamine, methamphetamine, benzoylecgonine, morphine, tetrahydrocannabinol (THC), and phencyclidine (PCP).

Description of the control line antibody: monoclonal goat anti-mouse

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Branan Medical Corporation Monitect Multiple Drug Screen
2. Predicate K number(s):
   k004034
3. Comparison with predicate:
   Both devices are for the qualitative determination of the same analyte(s) in the same matrix, and utilize the same cutoff concentration. Both are visually-read single use devices.

The reagent formulations vary between the two devices.

Similarities		
Item	**Device**	**Predicate**
Intended Use	Qualitative Detection of Drugs of Abuse	Same
Analytes and Cutoffs	Amphetamine: 1000 ng/mL Methamphetamine: 1000 ng/mL Benzoylecgonine: 300 ng/mL THC: 50 ng/mL Phencyclidine: 25 ng/mL Morphine: 2000 ng/mL	Amphetamine: 1000 ng/mL Methamphetamine: 1000 ng/mL Benzoylecgonine: 300 ng/mL THC: 50 ng/mL Phencyclidine: 25 ng/mL
Matrix	Urine	Same
Methodology	Lateral Flow Immunochromatographic	Same
Differences		
Item	**Device**	**Predicate**
Storage Temperature	2 – 30° C	20 – 30° C

K. Standard/Guidance Document Referenced (if applicable):

The sponsor did not reference any standards in their submission.

L. Test Principle:

The test employs lateral flow immunochromatographic technology.

Drug in the sample and drug-labeled conjugate (containing a chromagen) compete for antibody binding sites in the test area of the test strip. Binding of drug in the sample causes the absence of a line at the test area, i.e., a positive result. When drug is not present in the sample, the drug-labeled conjugate binds at the test line, resulting in formation of a line, i.e., a negative result. The absence or presence of the line is determined visually by the operator.

The device also has an internal process control which indicates that an adequate volume of sample has been added and that the immunochromatographic strip is intact.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
    a. Precision/Reproducibility:

The sponsor performed a precision study in which they compared results from a single-analyte device to the same assay as part of a six-drug card. For example, single benzoylecgonine results were compared to benzoylecgonine results when included as part of a six-

analyte device. The sponsor used one lot of product for each of the six individual assays and one lot of product for the multi-analyte assays.

Specimen description: drug free urine spiked with benzoylecgonine, Δ9-THC, morphine, PCP, d-amphetamine, d-methamphetamine
Number of days: one day each for both single and multiple analyte devices
Replicates per day: fifteen
Lots of product used: one for multiple analyte devices, one for each single-analyte device
Number of operators: three
Operator: manufacturer staff
Testing Facility: manufacturer

Results of the study are presented below:

Benzoylecgonine Precision Study Results as part of a six-drug device

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
0	15	15/0
150	15	15/0
225	15	11/4
300	15	0/15
375	15	0/15
450	15	0/15

Benzoylecgonine Precision Study Results with benzoylecgonine only

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
150	15	15/0
225	15	11/4
300	15	0/15
375	15	0/15
450	15	0/15

Tetrahydrocannabinol Precision Study Results as part of a six-drug device

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos

0	15	15/0
25	15	15/0
37.5	15	13/2
50	15	0/15
62.5	15	0/15
75	15	0/15

Tetrahydrocannabinol Precision Study Results with THC only

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
25	15	15/0
37.5	15	9/6
50	15	0/15
62.5	15	0/15
75	15	0/15

Morphine Precision Study Results as part of a six-drug device

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
0	15	15/0
1000	15	15/0
1500	15	14/1
2000	15	0/15
2500	15	0/15
3000	15	0/15

Morphine Precision Study Results with morphine only

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
1000	15	15/0
1500	15	13/2
2000	15	0/15
2500	15	0/15
3000	15	0/15

Phencyclidine Precision Study Results as part of a six-drug device

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
0	15	15/0

12.5	15	15/0
18.75	15	10/5
25	15	0/15
31.25	15	0/15
37.5	15	0/15

Phencyclidine Precision Study Results with phencyclidine only

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
12.5	15	15/0
18.75	15	10/5
25	15	0/15
31.25	15	0/15
37.5	15	0/15

Amphetamine Precision Study Results as part of a six-drug device

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
0	15	15/0
500	15	15/0
750	15	12/3
1000	15	0/15
1250	15	0/15
1500	15	0/15

Amphetamine Precision Study Results with amphetamine only

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
500	15	15/0
750	15	11/4
1000	15	0/15
1250	15	0/15
1500	15	0/15

Methamphetamine Precision Study Results as part of a six-drug device

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos

0	15	15/0
500	15	15/0
750	15	11/4
1000	15	0/15
1250	15	0/15
1500	15	0/15

Methamphetamine Precision Study Results with methamphetamine only

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
500	15	15/0
750	15	12/3
1000	15	0/15
1250	15	0/15
1500	15	0/15

The sponsor also performed a separate Inter-Lot Reproducibility study in which they compared three different lots of the six-drug devices at 0, 50, 75, 100, 125, and 150% of the cutoff for each analyte.

Specimen description: drug free urine spiked with benzoylecgonine, Δ9-THC, morphine, PCP, d-amphetamine, d-methamphetamine
Number of days: fifteen
Replicates per day: fifteen
Lots of product used: three
Number of operators: three
Operator: manufacturer staff
Testing Facility: manufacturer

	Lot 1		Lot 2		Lot 3	
	Positive	Negative	Positive	Negative	Positive	Negative
Amphetamine						
0% Cutoff	0	15	0	15	0	15
50% Cutoff	0	15	0	15	0	15
75% Cutoff	2	13	5	10	2	13
100% Cutoff	15	0	15	0	15	0
125% Cutoff	15	0	15	0	15	0
150% Cutoff	15	0	15	0	15	0
Methamphetamine						
0% Cutoff	0	15	0	15	0	15
50% Cutoff	0	15	0	15	0	15

	Lot 1		Lot 2		Lot 3	
	Positive	Negative	Positive	Negative	Positive	Negative
75% Cutoff	3	12	4	11	4	11
100% Cutoff	15	0	15	0	15	0
125% Cutoff	15	0	15	0	15	0
150% Cutoff	15	0	15	0	15	0
Benzoylecgonine						
0% Cutoff	0	15	0	15	0	15
50% Cutoff	0	15	0	15	0	15
75% Cutoff	2	13	3	12	3	12
100% Cutoff	15	0	15	0	15	0
125% Cutoff	15	0	15	0	15	0
150% Cutoff	15	0	15	0	15	0
THC						
0% Cutoff	0	15	0	15	0	15
50% Cutoff	0	15	0	15	0	15
75% Cutoff	2	13	1	14	3	12
100% Cutoff	15	0	15	0	15	0
125% Cutoff	15	0	15	0	15	0
150% Cutoff	15	0	15	0	15	0
Morphine						
0% Cutoff	0	15	0	15	0	15
50% Cutoff	0	15	0	15	0	15
75% Cutoff	4	11	4	11	2	13
100% Cutoff	15	0	15	0	15	0
125% Cutoff	15	0	15	0	15	0
150% Cutoff	15	0	15	0	15	0
Phencyclidine						
0% Cutoff	0	15	0	15	0	15
50% Cutoff	0	15	0	15	0	15
75% Cutoff	1	14	1	14	3	12
100% Cutoff	15	0	15	0	15	0
125% Cutoff	15	0	15	0	15	0
150% Cutoff	15	0	15	0	15	0

b. Linearity/assay reportable range:
Not applicable. The assay is intended for qualitative use.

c. Traceability (controls, calibrators, or method):
The device has an internal process control. Users are instructed to follow federal, state, and local guidelines when determining when to run external controls.

d. Detection limit:

Sensitivity of this assay is characterized by validating performance around the claimed cutoff concentration of the assay, including a determination of the lowest concentration of drug that is capable of producing a positive result. This information appears in the precision section, above.

e. *Analytical specificity:*
Cross-reactivity was established by spiking various concentrations of similarly structured drug compounds into drug-free urine. By analyzing various concentration of each compound the sponsor determined the concentration of the drug that produced a response approximately equivalent to the cutoff concentration of the assay. Results of those studies appear in the table(s) below:

Amphetamine

Drug Compound	**Response equivalent to cutoff in ng/mL**
d-amphetamine	1000
l-amphetamine	25,000
d-methamphetamine	> 400,000
l-methamphetamine	> 400,000
3,4-Methylenedioxyethylamphetamine(MDEA)	100,000
D,L 3,4-Methylenedioxymethamphetamine (MDMA)	> 400,000
3,4-Methylenedioxyamphetamine (MDA)	1200

Methamphetamine

Drug Compound	**Response equivalent to cutoff in ng/mL**
d-amphetamine	200,000
l-amphetamine	200,000
d-methamphetamine	1000
3,4-Methylenedioxyethylamphetamine(MDEA)	500
D,L 3,4-Methylenedioxymethamphetamine (MDMA)	1000
3,4-Methylenedioxyamphetamine (MDA)	> 200,000

Morphine

Drug compound	**Response equivalent to cutoff in ng/mL**
6-monoacetylmorphine	50
Codeine	2000
Heroin	2000
Hydrocodone	20,000
Hydromorphone	5000
Oxycodone	60,000
Morphine	2000

Drug compound	Response equivalent to cutoff in ng/mL
Morphine-3-β-glucuronide	2000
Ethylmorphine	50

Benzoylecgonine

Compound	Response equivalent to cutoff in ng/mL
Benzoylecogonine	300
Cocaethylene	50
Cocaine	300

Cannabinoids (THC)

Compound	Response equivalent to cutoff in ng/mL
11-Hydroxy-Δ^9-Tetrahydrocannabinol	2500
11-Nor-Δ^8-Tetrahydrocannabinol carboxylic acid	50
11-Nor-Δ^9-Tetrahydrocannabinol carboxylic acid	50
Δ^8-Tetrahydrocannabinol	7500
Δ^9 –Tetrahydrocannabinol	10,000
Cannabinol	10,000

Phencyclidine

Compound	Response equivalent to cutoff in ng/mL
Phencyclidine	25
4-hydroxyphencyclidine	1000
Phencyclidine Morpholine	50
Tenocyclidine	2000

The following compounds were evaluated for potential positive and/or negative interference with the assay. To evaluate for interference the sponsor added potentially interfering compounds to drug-free urine (to test for positive interference) and to urines at the cutoff concentration (to test for negative interference). All potential interferents were added at a concentration of 100 µg/mL. There were no deviations from the expected results.

Acetaminophen
Acetylsalicylic Acid
Amikacin
Amitriptyline
Ampicillin
Amoxicillin
Amobarbital
Amoxapine
Arterenol
Ascorbic Acid
Aspartame
Benzoic Acid
Butalbital
Caffeine
Celebrex
Chlorpheniramine
Chlorpromazine-HCL
Clobazam
Clomipramine
Cortisone
Cimetidine
Cholesterol
(-) Cotinine
Cyclobenzaprine

Deoxyephedrine	Ibuprofen	Procaine
Dextromethorphan	(+/) Isoproterenol	Propanol
Diethylpropion	Indomathacin	Promethazine
Diphenylhydantoin	Lidocaine	Phentermine
Diphenhydramine	Lorazepam	L-Phenylephrine
Diovan	Meperidine	Pseudoephedrine
Dopamine	Methylphenidate	Quinine
Doxylamine	Methadone	Quinidine
(-) Ephedrine	Methaqualone	Ranitidine (Zantac)
(-) Epinephrine	Naltrexone	Riboflavin
(+) Epinephrine	Niacinamide	Rofecoxib
(+/) Epinephrine	Nitrazepam	Sodium Salicylate
Erythromycin	Nordiazepam	Secobarbital
Ethanol	(+/) Norephedrine	Sulindac
Ecgonine	(-) Nicotine	Temazepam
Ecgonine Methyl Ester	Nicotinic Acid	Tryptophan
EDDP	Pendimetrazine	Tetracycline
Flunitrazepam	Penicillin G	Tetrahydrozoline
Furosemide	d-Propoxyphene	Theophylline
Histamine	Hydrochlorothiazide	Thioridazine
3-Hydroxytyramine	Promethazine	Trifluoperazine

There is the possibility that other substances and/or factors not listed above may interfere with the test and cause false results, e.g., technical or procedural errors.

The following endogenous compounds were evaluated for potential positive and/or negative interference with the assay. To evaluate for interference the sponsor added potentially interfering compounds to drug-free urine (to test for positive interference) and to urines at the cutoff concentration plus 25% (to test for negative interference). There were no deviations from the expected results.

Ascorbate	300 mg/dL
Bilirubin	1.0 mg/dL
Creatinine	500 mg/dL
Glucose	1500 mg/dL
Globulin	1500 mg/dL
Hemoglobin	300 mg/dL
Human serum albumin	500 mg/dL
Potassium	110 mEq/L
Sodium Chloride	6000 mg/dL
Uric Acid	23 mg/dL
Specific Gravity	1.003 and 1.030
pH	4, 5, 6, 7, 8, and 9

f. Assay cut-off:
The identified cutoff concentrations of the assays are the cutoff concentrations recommended for use by the Substance Abuse and Mental Health Services Administration (SAMHSA).

Characterization of how the device performs analytically around the claimed cutoff concentration appears in the precision section, above.

2. Comparison studies:

a. Method comparison with predicate device:
Because the candidate device was compared to a reference method, GC/MS, it was not compared to a predicate device.

Sample description: Unaltered clinical urine samples were evaluated.

Sample selection: Samples were purchased from a commercial laboratory, which supplied the GC-MS concentration for all negative and positive samples.

The studies included an adequate number of samples that contained drugs near to the cutoff concentration of the assay. Approximately 10% of the study samples are evenly distributed between plus and minus 50% of the claimed cutoff concentration.

Number of study sites: one
Type of study site(s): clinical setting
Operator description: clinical site staff

Candidate Device Results vs. stratified GC/MS Values - Amphetamine

A total of 110 samples (63 negative and 47 positive) were evaluated by the candidate device and by GC/MS.

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	3	5	42
Negative	58	2	0	0

GC/MS values used to categorize samples in this table are based on the concentration of amphetamine found in the sample.
% Agreement among positives is 100%
% Agreement among negatives is 95%

Candidate Device Results vs. stratified GC/MS Values - Methamphetamine

A total of 101 samples (60 negative and 41 positive) were evaluated by the candidate device and by GC/MS.

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	0	10	31
Negative	55	5	0	0

GC/MS values used to categorize samples in this table are based on the concentration of methamphetamine found in the sample.
% Agreement among positives is 100%
% Agreement among negatives is 100%

Candidate Device Results vs. stratified GC/MS Values - Benzoylecgonine

A total of 96 samples (54 negative and 42 positive) were evaluated by the candidate device and by GC/MS.

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	0	15	25
Negative	49	5	2	0

GC/MS values used to categorize samples in this table are based on the concentration of BE found in the sample.
% Agreement among positives is 95%
% Agreement among negatives is 100%

Candidate Device Results vs. stratified GC/MS Values - THC

A total of 96 samples (54 negative and 42 positive) were evaluated by the candidate device and by GC/MS.

Candidate	**Less** than half	**Near Cutoff**	**Near Cutoff**	**High Positive**

Device Results	the cutoff concentration by GC/MS analysis	**Negative** (Between 50% below the cutoff and the cutoff concentration)	**Positive** (Between the cutoff and 50% above the cutoff concentration)	(greater than 50% above the cutoff concentration)
Positive	0	1	6	36
Negative	50	3	0	0

GC/MS values used to categorize samples in this table are based on the concentration of THC found in the sample.
% Agreement among positives is 100%
% Agreement among negatives is 98%

Candidate Device Results vs. stratified GC/MS Values - Morphine

A total of 96 samples (55 negative and 41 positive) were evaluated by the candidate device and by GC/MS.

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	0	17	24
Negative	50	5	0	0

GC/MS values used to categorize samples in this table are based on the concentration of morphine found in the sample.
% Agreement among positives is 100%
% Agreement among negatives is 100%

Candidate Device Results vs. stratified GC/MS Values - Phencyclidine

A total of 97 samples (56 negative and 41 positive) were evaluated by the candidate device and by GC/MS.

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	4	16	25
Negative	49	3	0	0

GC/MS values used to categorize samples in this table are based on the concentration of PCP found in the sample.
% Agreement among positives is 100%

% Agreement among negatives is 93%

b. Matrix comparison:
Not applicable. The assay is intended for only one sample matrix.

3. Clinical studies:
   a. Clinical sensitivity:
   Not applicable. Clinical studies are not typically submitted for this device type.
   b. Clinical specificity:
   Not applicable. Clinical studies are not typically submitted for this device type.
   c. Other clinical supportive data (when a and b are not applicable):

4. Clinical cut-off:
   Not applicable.
5. Expected values/Reference range:
   Not applicable.

N. Proposed Labeling:
The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10

O. Conclusion:
The submitted information in this premarket notification is complete and supports a substantial equivalence decision.